Compliance Guidance for COMPUTED TOMOGRAPHY QUALITY CONTROL

New Jersey Department of Environmental Protection Bureau of Radiological Health PO Box 415 Trenton NJ 08625-0415

FAX 609-984-5811

Website: http://www.state.nj.us/dep/rpp

DEDICATION

This Guidance Document is dedicated to the memory of Joyce Zeisler. Her efforts to improve Quality Assurance Programs in New Jersey were instrumental in bringing about this program.

ACKNOWLEDGEMENTS

This Guidance Document was prepared through the efforts, advice and input of many people. We offer our thanks to all of the contributors. But in particular we thank the principal author: William J. Klimik, Radiation Physicist.

DISCLAIMER

This Compliance Guidance Document is not a substitute for the Department's regulations and compliance is not required with the procedures in this document. The procedures and/or methods described in this document are provided for information only. Performing these procedures does not necessarily constitute Department approval or guarantee compliance.

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INTRODUCTION

On January 16, 2001, the Department of Environmental Protection (Department) and the Commission on Radiation Protection adopted regulations (New Jersey Administrative Code 7:28-22) that require all facilities performing diagnostic x-ray procedures (radiology, fluoroscopy, x-ray bone densitometry or computed tomography) to develop and continually implement a Quality Assurance program. The regulations apply to equipment used on humans in hospital, medical, podiatric, chiropractic, industrial, school, and government facilities.

This document provides guidance for performing QC tests for computed tomography only. Additional compliance guidance documents are available for the QA Manual, Fluoroscopy and Radiographic quality control. See the section entitled, "Additional Documents Available" for information on receiving these documents.

A Quality Assurance (QA) program, which includes quality control tests, helps to ensure that high quality diagnostic images are consistently produced while minimizing radiation exposure. The QA program covers the entire x-ray system from machine, to processor, to view box. This program will enable the facility to recognize when parameters are out of limits, which will result in poor quality images and can increase the radiation exposure to patients. Simply performing the quality control tests is not sufficient. When quality control test results exceed established operating parameters, appropriate corrective action must be taken immediately and documented.

This guide is intended to assist the facility in setting up their QA Program and performing the quality control tests required to maintain high quality images and reduce patient exposure. This guide includes generally accepted procedures that the facility may use to perform the required tests. The procedures in this guide are not the only way to perform the tests. Alternative test procedures may be used without Department approval. However, all procedures being used must be documented in the facility's QA manual and meet the requirements of N.J.A.C. 7:28-22. In some cases, manufacturers' directions may be more appropriate than the generic procedures in this guide.

Product manufacturers, vendors, and service companies all have information available in the form of leaflets, videos and hands-on help. If the facility finds that they need more instruction than this guide provides, please use these companies and the medical physicist as resources. A bibliography that includes some of the available books on quality assurance is on page 34.

The responsibility for the quality control tests should be assigned to a QA program coordinator to ensure consistency in test methodology and interpretation of the data. More than one person may perform the tests but one person should assume overall responsibility for the day to day operation of the program. This leads to better understanding of when to repeat tests, call for service, or consult with the practitioner or medical physicist. The physician, medical physicist, and QC personnel, working together as a team, are the key to providing optimum quality radiographic images.

Due to the importance of quality control in diagnostic imaging, it is recommended that the appropriate facility personnel review the control tests, data and images quarterly.

The establishment and maintenance of a Quality Assurance program will ensure consistent image quality over the lifetime of the CT system. Quality Assurance begins with baseline performance data acquired during CT system installation including scanning a phantom under a prescribed set of conditions. These baseline images should be saved and used as a visual comparison with the daily QA checks. The baseline values will provide an objective way to monitor quality by repeating these tests or procedures on a regular frequency to detect changes in image quality values before the problem affects patient images. Early intervention could save time, money and prevent unnecessary patient exposure to radiation.

Computed Tomography Quality Control

Each registrant of diagnostic computed tomography (CT) equipment used in the healing arts must develop and continuously implement a quality assurance program. The required basic elements of the regulations are listed below.

BASIC ELEMENTS OF CT QUALITY CONTROL

- Quality Assurance Program Manual.
 See Compliance Guidance Document for the Quality Assurance Program Manual.
- 2. Quality control tests, see TABLE 3
- 3. Tests in TABLE 3 (items 1-11) must be performed by licensed radiological technologist, a qualified medical physicist, or a trained service technician.
- 4. Keep records for all tests performed, see TABLE 2.
- 5. If conventional film processing is used and if any of the test results from item 2 in TABLE 3, Computed Tomography Quality Control Requirements, indicate that the film processing does not meet the standards in TABLE 3, the registrant must immediately initiate steps to bring the processing into compliance. Films may not be processed until the processing meets these standards.
- 6. If laser film imaging is used and if any of the test results from item 5 in TABLE 3, Computed Tomography Quality Control Requirements, indicate that the laser film printer does not meet the standards in TABLE 3, the registrant must immediately initiate steps to repair the laser film printer to meet the standards. Films may not be processed until the processing meets the standards.
- 7. If test results for items 3,4,6,7, and 8 in Table 3 do not meet standards, then immediately initiate steps to repair CT equipment to meet standards. Repairs must be completed within 30 days. Keep records of all corrective actions.
- 8. If test results for items 9,10, and 11 in Table 3 do not meet standards, then immediately initiate steps to repair CT equipment to meet standards. Repairs must be completed within 15 days. Keep records of all corrective actions.
- 9. Medical Physicist QC Survey, TABLE 3 (item 12), must be performed by a qualified medical physicist for the supervision of quality assurance programs for computed tomography. See TABLE 6.
- 10. If any of the Computed Tomographic QC Survey test results from items 1 through 4 in TABLE 6, Medical Physicist's Computed Tomography QC Survey, indicate that the CT equipment does not meet the standards established in TABLE 6, the registrant must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 15 days. Keep records of all corrective actions.
- 11. If any of the Computed Tomographic QC Survey test results from items 5 through 11 in TABLE 6, Medical Physicist's Computed Tomography QC Survey, indicate that the CT equipment does not meet the standards established in TABLE 6, the registrant must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 30 days. Keep records of all corrective actions.
- 12. QA program review, TABLE 3 (item 13), must be done by the facility's QA team and the qualified medical physicist.

The regulation requires that each facility with CT equipment perform, or have performed, the tests in TABLE 3, "Computed Tomography Quality Control Requirements" (page 11), at least at the frequency specified, and maintain records of the test results.

FREQUENCY

The frequency of tests specified in TABLE 3 is the minimum frequency. The frequency of quality control tests may need to be increased depending on many factors including the age and stability of the x-ray equipment and film processing equipment, as well as the number of problems being encountered.

Tests may always be performed at a GREATER frequency than required by N.J.A.C. 7:28-22. Tests may NOT be performed at frequencies LESS than required in N.J.A.C. 7:28-22 unless approved by the Department as outlined in N.J.A.C. 7:28-22.3(f). For example, if the facility decides to test Low Contrast Resolution weekly, this new frequency must be documented in the facility's QA manual and the test data needs to be recorded appropriately.

CONSISTENCY IS THE KEY!

After each link (CT unit, laser film printer, etc.) in the imaging chain is optimized, a working QA program will provide warning flags to the QA program coordinator when something goes awry. If the coordinator finds, during the daily review, that the established tolerances are exceeded, the test or tests must be repeated to verify the results, then corrective action must be taken. The coordinator must be capable of identifying problems and willing to resolve them as they occur, or the QA program will not provide the intended benefits.

COMPETENCY

The registrant, per N.J.A.C. 7:28-22.5(d), must ensure that all individuals, performing any of the CT quality control tests, have an appropriate level of training to perform the tests competently. The registrant shall ensure that individual performing quality control tests described in TABLE 3, Computed Tomography Quality Control Requirements, is a licensed radiologic technologist, a qualified medical physicist, or a trained service technician. The facility must ensure that there are sufficient trained personnel so that there is always someone available (i.e. to cover vacation and sick time) to perform the necessary testing.

TRAINING OPTIONS

The registrant may train their own personnel. This assumes that the registrant is competent in the particular procedure and is able to convey this knowledge adequately to the personnel. Product manufacturers, vendors, and service companies have training aids available in the form of leaflets, and videos. Companies whose sole purpose is training as well as service and repair companies and the facility's medical physicist can provide seminars and training courses ranging from a few hours to several days or more on the how to of Quality Control tests. Adequate training of personnel will ensure that the tests are performed correctly and consistently.

Using This Guidance Document

This document is intended to provide guidance for performing QC tests for computed tomography only. Additional compliance guidance documents are available for the QA Manual, Fluoroscopy and Radiographic quality control. See the section entitled, "Additional Documents Available" for information on receiving these documents. Several other documents are listed in the last section that the facility might find useful.

A detailed description of each required test follows in the order listed in TABLE 3. This is the same table that appears in the regulation at N.J.A.C. 7:28-22.7.

Records of Quality Control test results, corrective actions, Medical Physicist's QC Survey, and Quality Assurance Program Review must be maintained for at least the time period specified in TABLE 4 (page 11).

ADDITIONAL DOCUMENTS AVAILABLE

Compliance Guidance for QA Manual: this document provides guidance in setting up a QA program, assignment of QC testing to various individuals, and the information required to be maintained at the facility.

Compliance Guidance for Radiographic Quality Control: this document contains detailed descriptions for performing the QC tests required for radiographic machines, film processing and laser film printers.

Compliance Guidance for Fluoroscopic Quality Control: this document contains detailed descriptions for performing the QC tests required for fluoroscopic machines.

Radiation Safety Manual: this document provides guidance to setting up the radiation safety manual as required by N.J.A.C. 7:28-15.9(a) 8.

List of Qualified Medical Physicists for QC Surveys: certain tests must be performed by or under the direction of a medical physicist meeting certain educational and experience requirements. This document contains a current list of individuals who meet the requirements of N.J.A.C. 7:29-22.

List Of Qualified Individuals For The Performance Of Radiation Safety Surveys Of The Environs: this document contains the names of individuals who meet the educational and experience requirements in N.J.A.C. 7:28 to perform radiation safety surveys of the environs on x-ray equipment. The individuals on this list are not necessarily the same individuals as on the qualified medical physicists for QC surveys list.

Commercial Personnel Monitoring Services: this document contains the names of companies that provide radiation monitoring equipment (badges).

Assemblers list: this document contains a list of vendors who sell and repair x-ray equipment.

NOTE: List of vendors for QC equipment is in this document in the Vendor section

Copies of these documents can be obtained from the Department by any of the following methods. If faxing or mailing a request, please be sure to include your name and mailing address or fax number. **Due to the length of the compliance guidance documents, we are not able to fax them.**

Internet Web site: http://www.state.nj.us/dep/rpp

Fax a request to: 609-984-5811

Mail a request to: New Jersey Department of Environmental Protection

Bureau of Radiological Health

PO Box 415

Trenton NJ 08625-0415

TABLE 3 Computed Tomography Quality Control Requirements

(To be performed by a licensed radiological technologist, a qualified medical physicist, or a trained service technician)

Item	Required Test or Procedure	Frequency	Standard						
1.	Equipment Function: Indicators, Mechanical, and other Safety Checks. Warm-up	Daily, each day x-rays are taken	Must work properly						
2.	For film processing, items 2, 6, 8, and 11 QC tests as specified in Table 1, Radiographic Quality Control Requirements	As specified in Table 1, Radiographic Quality Control Requirements	As specified in TABLE 1, Radiographic Quality Control Requirements						
3.	CT Number for Water	Daily	CT equipment or phantom manufacturers' specifications						
4.	Field Uniformity	Daily	CT equipment or phantom manufacturers' specifications						
5.	Laser Film Printer Quality Control	Weekly	Recommended control limits $\frac{SMPTE\ Test\ Pattern}{O\%\ patch\ 2.45\pm\ 0.15\ OD} = \frac{Inverted\ gray\ scale}{O\%\ patch\ 2.50+\ 0.15\ OD} = \frac{Inverted\ gray\ scale}{O\%\ patch\ 2.$						
6.	Low Contrast Resolution	Initially and Monthly	CT equipment or phantom manufacturers' specifications						
7.	High Contrast Spatial Resolution	Initially and Monthly	CT equipment or phantom manufacturers' specifications						
8.	Noise	Initially and Monthly	CT equipment or phantom manufacturers' specifications						
9.	Table Position Indicator Accuracy	Initially and Monthly	±2 mm						
10.	Scan Increment Accuracy	Initially and Monthly	±1 mm						
11.	Scan Localization Light Accuracy	Initially and Monthly	± 5 mm						
12.	Medical Physicist's QC Survey	Initially and annually	As required in N.J.A.C. 7:28-22.10						
13.	Quality Assurance Program Review	Initially and annually	As required in N.J.A.C. 7:28-22.4(a)7						

Table 4 Records Retention								
Record Type	Minimum Retention Time							
EACH corrective action, repair and service	Two Years							
Test Results for items 2 though 11 in TABLE 3, Computer Tomography Quality Control Requirements. Recommend retaining test results for items 2 though 11 in TABLE 3, in either a written, digital or film record.	One Year							
Radiation Safety Survey of the Environs	As long as machine is owned plus one year							
INITIAL Medical Physicist QA Survey	Permanently maintained							
ANNUAL Medical Physicist QA Survey	Two Years							
Quality Assurance Program Review	Two Years							

Equipment Warm-up Procedure

Test Frequency: Each Day of Operation

Standard: Warm up tube; ensure equipment is working properly.

Each day during the Computed Tomography (CT) system warm-up, and before scanning the first patient, check for visual indication of x-ray beam-on, tomographic plane indication (laser or light source), table and gantry mechanical integrity and the electrical safety of the CT system. Malfunctions and unsafe conditions must be corrected promptly.

Procedure 1 Equipment Warm-up

Turn on system.

Follow the CT manufacturer's recommended warm up procedure.

CORRECTIVE ACTION:

If an unusual noise, spark or other unusual event is noted, the equipment should not be used until the situation has been corrected and the equipment is operating normally. Contact the CT Service Company to repair. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

There are no records required of daily equipment warm-up.

Film Processing

Hard-copy films of images using a video-base camera and automated chemical processor

Facilities performing hard-copy films of images using a Video-Base Camera and automated chemical processor must also perform the following tests:

Processor Quality Control Processor Maintenance and Chemical Solutions Film and Chemical Shelf Life Analysis of Fixer Retention

Generic procedures for performing these tests can be found in the Compliance Guidance for Radiographic Quality Control document available from the Department.

Copies of this document can be obtained from the Department by any of the following methods. If faxing or mailing a request, please be sure to include your name and mailing address or fax number. Due to the length of the compliance guidance documents, we are not able to fax them.

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CT Number for Water

Test Frequency: Daily

Standard: CT manufacturer's specifications or phantom manufacturer's specifications

This test is the day to day consistency check of CT calibration number for water. When you correctly image and analyze the water phantom, you should see a CT number for water of 0 ± 3 or follow the CT manufacturer's specifications. The computer tomography system assigns numbers, also called (HU) Hounsfield Units, to the attenuation values of x-ray passing though a variety of material densities. The computer software makes the attenuation visible by assigning shades of gray to the selected groups of numbers. The test for CT Number for Water in the phantom represents the standard against which you can track the system constancy.

Procedure 3 CT Number for Water

Equipment Required:

Manufacturer's water phantom or other commercially available test phantom.

Follow the CT manufacturer's or phantom manufacturer's procedure to correctly image and analyze the water phantom. Test results must be documented and maintained for at least one year. The CT number for water should be recorded and compared each day to the established specifications.

CORRECTIVE ACTION:

If the measurements indicate the CT number for water exceeds specifications, have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy, film and digital copy of initial CT Number for Water testing. Keep written record of all daily testing for CT Number for Water for at least one year.

Field Uniformity

Test Frequency: Daily

Standard: CT Manufacturer's Specifications or Phantom Manufacturer's Specifications

This test determines the spatial uniformity of CT numbers in a uniform medium. The uniformity test is a simple and direct approach to determining the accuracy of the image reconstruction process. Scan plane uniformity is evaluated with phantoms constructed of solid acrylic or other water simulating plastic or a phantom filled with distilled water. To evaluate the scan plane uniformity, a phantom with appropriate dimensions and uniform attenuation is scanned under simulated clinical conditions. In an image of the 20-cm diameter phantom filled with a uniformly attenuating medium, the mean CT number of any 100 pixels should not differ by more than 5 from the mean CT number of any other 100 pixels. The uniformity image can be very helpful in identifying the presence of image perturbations such as beam hardening artifacts, detection nonuniformity rings, etc.

Procedure 4 Field Uniformity

Equipment Required:

The Manufacturer's uniformity phantom or other commercially available uniformity test phantom of 15-21cm and 30-32cm diameter.

Follow the CT manufacturer's procedure or phantom manufacturer's procedure. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measurements indicate a change in values for uniformity beyond the CT equipment or phantom manufacture's specifications, have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy, film and digital copy of initial Field Uniformity testing. Keep written record of all daily testing for Field Uniformity for at least one year.

Laser Film Printer Quality Control

<u>Test Frequency – Weekly</u>

Standard

SMPTE Test Pattern	Inverted gray scale
0% patch 2.45± 0.15 OD*	0% patch 2.50+ 0.15 OD
10% patch 2.10± 0.15 OD	10% patch 2.25 ± 0.15 OD
40% patch 1.15± 0.15 OD	40% patch 1.35 ± 0.15 OD
90% patch 0.30± 0.08 OD	90% patch 0.30± 0.08 OD
The 5% patch should just be vi	isible inside of the 0% patch.
The 95% patch should just be	visible inside of the 100% patch.

*OD = Optical Density

In most clinical settings, the physician makes the diagnosis by reading the images from a transparency recorded with a multiformat camera. The transparency should reproduce the quality and gray scale of the original image displayed on the system monitor. The following procedure uses the Society of Motion Picture and Television Engineers (SMPTE) digital test pattern. This pattern is supplied with most laser printers or it can be obtained from accessory vendors.

The N.J.A.C. 7:28-22.6 specifies that laser film printer QC MUST be performed weekly.

Each laser film printer in the facility must be tested. Having one laser film printer in control does not ensure that all other laser printers in the facility are in control. QC must be performed on laser film printers used in hospital emergency departments or mounted in mobile vans.

The facility must ensure that if the densitometer is broken, out for calibration or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the laser film printer is operating within control limits. There is a list of options the facility may consider for meeting this requirement on page 41.

Before you begin your laser film printer quality control program, you must:

Select an Appropriate Densitometer

A densitometer is a device that measures the optical density of the developed SMPTE test pattern. Evaluation of the laser printer requires that the SMPTE test pattern is processed, the densities measured with the densitometer, and these measurements compared to a standard or past values.

The patches of the SMPTE test pattern film must be read with a densitometer. It is inappropriate to visually compare the SMPTE test pattern patches. The densitometer should provide sufficient range to properly read the SMPTE test pattern produced.

To obtain the best results, you must:

Check Densitometer Calibration Daily

The calibration of the densitometer should be checked daily before use to ensure that it is functioning properly. The densitometer manufacturer supplies a calibrated step tablet when the unit was purchased. Carefully follow the manufacturer's instructions for using this calibration tablet to verify that the densitometer is still calibrated over the range specified.

If the calibration tablet check indicates that the densitometer is out of calibration, most densitometers have a screw adjustment that can be used for making minor changes. Follow the manufacturer's instructions for performing this adjustment. If the densitometer cannot be brought into calibration by facility adjustment, the densitometer must be returned to the manufacturer for a more thorough calibration or repair.

If the densitometer needs to be calibrated or repaired, it must be returned to its manufacturer or another vendor. A list of vendors who calibrate sensitometers and densitometers is on page 38.

The facility must ensure that if the densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the laser film printer is operating within control limits. There is a list of options the facility may consider for meeting this requirement on page 41.

When reading any step on the calibration strip, the density should be measured in the center of the step. The values given for the calibration strip and those taken daily should agree within the manufacturer's specifications (usually \pm 0.02 or \pm 0.03) for all steps of the strip.

Use Control Charts

Control charts are needed to plot and review acquired data. Whenever a data point reaches or exceeds the control limits, the test should be repeated immediately. If the repeated measurement still reaches or exceeds the control limits, then <u>immediate corrective action is required</u>. The out-of-control data point should be circled, the cause of the problem noted, corrective action performed, documented, and then retested and the in-control data point plotted.

The initials of the individual who performed the evaluation of the laser film printer and the date the test was performed should be indicated. Notes regarding changes in operating conditions should be recorded on the control chart.

The control chart is also useful in detecting trends that indicate an unstable process. A trend is an upward or downward change in the measured data when three data points move in the same direction. The cause of trends should be investigated before the control limits are reached or exceeded.

Establish Operating Levels and Control Limits

When establishing a laser printer quality control program, it is necessary to determine the operating levels and control limits. The operating level is the level normally expected. The control limits are the extreme ranges of acceptable operation. If control limits are exceeded, the quality control test should be repeated. If the result is still out of limits, corrective action must be taken **before** patient films are processed.

DO NOT widen the control limits since the data indicates that the laser film printer is out of control and corrective action is essential. These limits are set by NJ State regulation.

Procedure 3A Establishment of Laser Film Printer Quality Control Operating Levels

Frequency: Initial setup and when significant change is made in imaging procedures such as

different type of film, chemicals, or processing conditions.

As determined by procedure 3A, the laser film printer quality should be consistent over time and match the gray scales presented on monitor.

If possible, the medical physicist should assist with the initial establishment of the laser film printer quality control operating levels. The medical physicist should determine the most appropriate gray scale test pattern to use for the facility's laser film printer system configuration or acquire a stepwedge phantom image if no gray scale test pattern is available.

Equipment Required:

Densitometer

Form 1 Laser Film Printer Quality Control Chart (page 42)

Gray Scale test Pattern - SMPTE (Society of Motion Picture and Television Engineers)

A. Video Monitor Setup

Must be performed on EACH video monitor (operator's console, physician's console, etc.) so that the all appear similar.

- 1. Clean front surface of video monitor, including the front and back surfaces of any antireflective screens present, with a soft cloth and an appropriate cleaner.
- 2. Reduce room lighting to that usually used for viewing studies.
- 3. Display SMPTE test pattern on monitor.
- 4. Adjust the window width to just show the range of numbers of the test pattern.
- 5. Depending on the software, adjust the window level to either the lower or middle value so that the entire pattern is seen.
- 6. Turn both the brightness and contrast controls completely counterclockwise.
- 7. Turn the brightness control clockwise until the video raster pattern is just visible on the monitor.
- 8. Turn the contrast control clockwise until the image is bright and clear. Both the 95% and 100% patches must be clearly separated. Do not increase contrast beyond the point where the alphanumerics become blurred or streaked on the display.

- 9. The displayed image must show:
 - a. The 5% patch must be just visible inside the 0% patch.
 - b. The area of the 0% patch should be almost black with raster lines just barely visible.
 - c. The 95% patch must be visible inside the 100% patch.
 - d. The alphanumerics should be clear and sharp.
- 10. Record the window and level settings so that they can be used for the Weekly Laser Film Printer Quality Control.

B. Laser Printer Setup

- 1. Send the SMPTE test pattern to the laser film printer using the largest most commonly used image format (1 on 1 or 4 on 1).
- 2. Process film if applicable.
- 3. With the film on a view box and the same image on the monitor, visually compare the film gray scale densities on the film to those on the monitor.
- 4. Make necessary adjustments to the laser film printer settings to match film appearance to monitor appearance using manufacturer's recommended procedures. Also compare a variety of digital patient images printed on film with the same images as displayed on the monitor. This will ensure that the patient images appear the same on the monitor and on film.
- 5. Ensure that the 5% patch is just visible inside of the 0% patch and the 95% patch is just visible inside of the 100% patch.
- 6. If the 5% patch is not just visible inside of the 0% patch and the 95% patch is not just visible inside of the 100% patch, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until laser film printer is operating within limits set by the regulations.
- 7. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.
- 8. Measure the optical density (OD) with the densitometer of the 0%, 10%, 40%, and 90% patches. By regulation the OD of:
 - a. The 0% patch must be 2.45 ± 0.15 OD
 - b. The 10% patch must be 2.10 ± 0.15 OD
 - c. The 40% patch must be 1.15 ± 0.15 OD
 - d. The 90% patch must be 0.30 ± 0.08 OD
- 9. If the optical densities of the four patches in step 7 are not at the regulatory limits, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until laser film printer is operating within limits set by the regulations. Record the OD values on the Laser Film Printer Quality Control Chart (Form 4).
- 10. Determine acceptable limits for each patch and record on the Laser Film Printer Quality Control Chart (Form 4).
 - a. The 0% patch limits are 2.30 OD and 2.60 OD
 - b. The 10% patch limits are 1.95 OD and 2.25 OD
 - c. The 40% patch limits are 1.00 OD and 1.30 OD
 - d. The 90% patch limits are 0.22 OD and 0.38 OD

Procedure 3B Weekly Laser Film Printer Quality Control

Frequency: Weekly

Equipment Required:

Densitometer

Form 1 Laser Film Printer Quality Control Chart (page 42)

SMPTE (Society of Motion Picture and Television Engineers) test pattern (this test pattern is usually supplied with the laser printer or it can be purchased from a vendor)

- 1. Display the gray scale test pattern on the monitor and verify that the window and level settings have been set to values established in **Procedure 3A Establishment of Laser Film Printer Quality Control Operating Levels**.
- 2. Print the image on film using the image format established in **Procedure 3A**.
- 3. Ensure that the 5% patch is just visible inside of the 0% patch and the 95% patch is just visible inside of the 100% patch.
- 4. If the 5% patch is not just visible inside of the 0% patch and the 95% patch is not just visible inside of the 100% patch, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until laser film printer is operating within limits set by the regulations.
- 5. Record on Laser Film Printer Quality Control Chart (Form 1).
- 6. Turn on the densitometer and follow manufacturer's procedures for warm up. Follow manufacturer's procedure to zero the densitometer. This is usually done by holding down the optical sensory arm and pressing the NULL button until 0.00 is displayed. The densitometer must be zeroed before each use. The densitometer must be calibrated before each use by using the calibration tablet supplied by the manufacturer. If the densitometer has several aperture sizes, use the 2mm aperture.
- 7. Measure the optical density with the densitometer at the 0%, 10%, 40%, and 90% patches on the film.
- 8. Record the OD values on the Laser Film Printer Quality Control Chart (Form 1) and determine if any of the data points exceed the control limits.
- 9. Circle the out-of-control data point(s).
- 10. When a density step is found to be out of control limits, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until laser film printer is operating within limits set by the regulations.
- 11. Note the cause of the problem on the reverse of the Laser Film Printer Quality Control Chart (Form 1) and plot the in-control data point.
- 12. Determine if there are any trends, i.e., three or more data points moving in one direction (either upward or downward). If trends are present but the data points have not, as yet, exceeded the control limits clinical images can be processed. However, it will be necessary to determine the cause of the trend and to monitor the laser film printer closely to ensure that the control limits are not exceeded.

CORRECTIVE ACTION: Immediate action must be taken to correct any problems. When a density step is found to be out of control limits, first recalibrate the laser film printer according to the manufacturer's recommended procedure and reprint the SMPTE test pattern. If the density steps are still out of control limits, seek service adjustment of the laser film printer. Films must not be processed until laser film printer is operating within limits set by the regulations. All corrective actions must be completed before patient films are taken, documented and records retained for a minimum of 2 years.

RECORDS:

Keep written record of weekly Laser Printer testing for at least one year. Recommend maintaining a copy of initial SMPTE film test. Recommend maintaining last six weeks of SMPTE film testing.

Low Contrast Resolution

Test Frequency: Initially and Monthly

Standard: CT Manufacturer's Specifications or Phantom Manufacturer's Specifications

This test determines the capability of the scanner to discriminate low contrast objects. Since much relevant soft tissue detail is low contrast in nature; this is perhaps the most clinically important test. The visibility of low contrast objects is constrained mainly by amplitude and frequency characteristics of the image noise. In CT, contrast is defined as the difference in CT numbers values between two structures. Subject contrast in CT is simply the difference in average CT numbers between two adjacent regions of the image.

Procedure 6 Low Contrast Resolution

Equipment required:

Manufacturer's low contrast detectable test phantom or other commercially available low contrast detectable test phantom.

Follow the CT manufacturer's procedure or phantom manufacturer's procedure. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measurements indicate a change in QA values for low contrast resolution beyond the CT equipment or phantom manufacturer's specifications, have the imaging physicist run more detailed tests or contact your service representative. Document steps taken to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy, film and digital copy of initial Low Contrast Resolution testing. Keep Low Contrast Resolution written record of monthly testing for one year. Recommend maintaining pervious six months of film and/or digital copy of monthly testing for Low Contrast Resolution.

High Contrast Spatial Resolution

Test Frequency: Initially and Monthly

Standard: CT Manufacturer's Specifications or Phantom Manufacturer's Specifications

This test determines the high contrast spatial frequency limits of the CT scanner under various conditions. In any CT system, the image noise and blurring place upper limits on the spatial frequencies of the patient reproduced in the image. The relative importance of noise and blurring is a function of image contrast. For very low contrasts, objective visibility is primarily constrained by image noise, and is independent of blurring effects. At very high contrasts, noise effects are negligible, and object visibility is constrained only by blurring sources. Between these extremes, as contrast increases, the effect of noise on object visibility becomes less important while the influence of blurring source grows. In a patient, visualized tissues span a wide range of contrasts, therefore the evaluation of spatial frequency limits of a scanner should span a similar range.

Procedure 7 High Contrast Spatial Resolution

Equipment required:

Manufacturer's high contrast test phantom or other commercially available high contrast test phantom.

Follow the CT manufacturer's procedure or phantom manufacturer's procedure. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measurements indicate a change in QA values for high contrast beyond the CT equipment or phantom manufacturer's specifications, have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy, film and digital copy of initial High Contrast Spatial Resolution testing. Keep written record of monthly testing for High Contrast Spatial Resolution for one year. Recommend maintaining pervious six months of film and/or digital copy of monthly testing for High Contrast Spatial Resolution.

Noise

Test Frequency: Initially and Monthly

Standard: CT Manufacturers' Specifications or Phantom Manufacturer's Specifications

This test assesses the level of noise under simulated clinical conditions and its variation with different scanning parameters. Noise refers to the fluctuations in CT numbers in a uniform medium around its average value. Image noise is analogous to quantum mottle in conventional radiography and is a part of the signal, which does not add to information. Noise limits the perceptibility of low contrast detail. The lower the noise, the better visibility of low contrast objects.

Procedure 8 Noise

Equipment Required:

Manufacturer's head and body water phantoms or other commercially available head and body water phantoms.

Follow the CT manufacturer's procedure or phantom manufacturer's procedure. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measurements indicate a change in QA values for noise beyond the CT equipment or phantom manufacturer's specifications, have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 30 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy, film and digital copy of initial Noise testing. Keep written record of monthly Noise testing for one year. Recommend maintaining pervious six months of film and/or digital copy of monthly Noise testing.

Table Position Indicator Accuracy

Test Frequency: Initially and Monthly

Standard: ±2 mm

This test assesses the amount of relative table displacement between successive scans by measuring the actual displacement the table traveled between scans. The CT operator must be able to accurately move patients to the indicated distance between scans from the operator control console. The true position of the bed should agree to within ± 2.0 mm of the indicated position. If no manufacturer's procedure is available, then use the procedure below.

Procedure 9 Table Position Indicator Accuracy

Equipment required:

30 cm. ruler

14x17 therapy localization film

suitable ridged support for film backing plate

measurements taken with a mass of 100 kilograms or less on the patient table

To perform this procedure, tape film to a suitable rigid support and set scan width to 5mm. Scan the film at a typical starting position. Then from the operator control console increment the tabletop 20mm in a positive direction and scan the film. Then repeat incrementing the table top another 20mm and scan the film again. Repeat incrementing the table top another 20mm and scan the film again. Process the film and measure the distance between the slices, measuring from the beginning of the first slice to the beginning of the next slice, check the distance between the other consecutive slices.

Repeat the same procedure in the negative direction. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measured distance between consecutive slices exceeds the operator set distance by more than 2mm; have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy of initial Table Position Indicator Accuracy testing. Keep written record of monthly testing for Table Position Indicator Accuracy for one year.

Scan Increment Accuracy

Test Frequency: Initially and Monthly

Standard: ±1 mm

This test determines of the deviation of indicated versus actual scan increment. Under computer control from operator's console the patient table must be able to accurately and reproducibly move the patient to any indicated position in the scan field. Accuracy is critical since it influences the multi-scan dose and determines relative locations of image sections. If no manufacturer's procedure is available, then use the procedure below.

Procedure 10 Scan Increment Accuracy

Equipment required: 10-30 cm ruler with mm ruling bent paper clip for a pointer adhesive tape

To perform this procedure, tape a ruler along the tabletop edge, near the foot end of the table. Tape the end of the paper clip onto the table frame opposite the middle of the ruler with the pointer directed at ruler midpoint. Zero table position. Place on the table 70-100kg, or have an assistant lie on the table. This gives the table the weight it needs to simulate a patient. From control console, note the table position. Under computer control, move the tabletop 300mm in one direction, and then back to the original position. The tabletop should go back to the original position. At this point, measure the difference, if any indicated by the pointer and the ruler. Repeat this measurement again in the opposite direction to be sure that the measurements are consistent. Record results.

CORRECTIVE ACTION:

If the measured deviation between the starting position slice and the incremented slice returned to the starting position measures greater than ± 1 mm, then have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy of initial Scan Increment Accuracy testing. Keep written record of monthly Scan Increment Accuracy testing for one year.

Scan Localization Light Accuracy

Test Frequency: Initially and Monthly

Standard: ±5 mm

This quality control test shows the congruence of scan localization light/laser and x-ray field scan plane. Patient anatomy to be scanned is often defined by scan alignment lights. Alignment lights may be located within the gantry at the slice plane, outside the gantry at a reference distance from the scan plane, or both. If both internal and external alignment lights are supplied, and are independently aligned, both should be tested. If no manufacturer's procedure is available, then use the procedure below.

Procedure 11 Scan Localization Light Accuracy

Equipment:

14x17 therapy localization film suitable rigid support for film backing plate adhesive tape and a sharp pin or needle.

Tape film to a suitable ridged support. Align the film to the long axis of the table, and raise the table to the head scan position. Turn on the internal alignment light and mark the location on film by piercing the film pack with a pin at several points along the middle of illuminated line. Scan the film pack at the inner light location using the narrowest slice setting: $\cong 1.0$ mm. Reposition the film and repeat procedure for external light, but put a unique pattern of pin pricks near each illuminated line for easy identification. Scan the film pack at the external light location using the narrowest slice setting: $\cong 1.0$ mm. Develop the film. Measure alignment error from pierced hole in processed film to midpoint of the radiation field. Error should not exceed ± 5.0 mm. Test results must be documented and maintained for at least one year.

CORRECTIVE ACTION:

If the measured alignment error from holes in the processed film to midpoint of radiation field measures greater than ± 5.0 mm than have the imaging physicist run more detailed tests or contact your service representative. Document steps to repair the CT equipment to meet standards. All corrective actions must be completed within 15 days, documented and records of each corrective action, repair and service maintained for at least 2 years.

RECORDS:

Permanently maintain a written copy of initial Scan Localization Light Accuracy testing. Keep written record of monthly Scan Localization Light Accuracy testing for one year.

Medical Physicist's Computed Tomography QC Survey

Test Frequency: Initially and Annually

Standard: As required in N.J.A.C. 7:28-22.7(1)

The QC Survey is a series of measurements performed by the physicist to verify that a CT system conforms to manufacturer's specifications and state regulations. The physicist's primary concerns are image quality, radiation dose and radiation protection. The QC Survey will test performance characteristics that can be quantified by a medical physicist using widely available instruments and phantoms.

Procedure 12 MEDICAL PHYSICIST'S COMPUTED TOMOGRAPHY QC SURVEY

The registrant must ensure that a qualified medical physicist for the supervision of quality assurance programs for computed tomography equipment has performed and documented all the tests in Table 6. The Medical Physicist's Computed Tomography QC Survey must include the tests identified in the TABLE 6, Medical Physicist's Computed Tomography QC Survey. If the standard for any test in TABLE 6 refers to a manufacturer's specification and no such specification exists, then that standard does not apply.

CORRECTIVE ACTION:

Document steps to repair the CT equipment to meet standards. If any test results form items 1 through 4 in Table 6, indicate that the CT equipment does not meet the standards established in Table 6, you must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 15 days. If any test results form items 5 through 11 in Table 6, indicate that the CT equipment does not meet the standards established in Table 6, you must immediately initiate corrective actions to meet the standards. All corrective actions must be completed within 30 days. For item 12 in Table 6, the medical physicist must ensure that both the adult and pediatric scan protocols are separate and unique.

Records:

The registrant must ensure that the initial Medical Physicist's Computed Tomography QC Survey is permanently maintained and the records of the annual Medical Physicist's Computed Tomography QC Survey are maintained for at least two years. Permanently maintain a written copy, film and digital copy of initial Medical Physicist's Computed Tomography QC Survey. Maintain for at least two years a written copy, film and digital copy of Annual Medical Physicist's Computed Tomography QC Survey.

	TABLE 6 MEDICAL PHYSICIST'S COMPUTED TOMOGRAPHY QC SURVEY										
Item	Test	Standard									
1.	Scan Increment Accuracy	±1mm									
2.	Scan Localization Light Accuracy	±5mm									
3.	Patient Dose (Multiple Scan Average Dose-MSAD or Computed Tomography Dose Index-CTDI)	CT equipment manufacturers' specifications and scan protocol or phantom manufacturers' specifications									
4.	Pre-Patient Collimation Accuracy	Manufacturers' specifications									
5.	Contrast Scale	CT equipment or phantom manufacturers' specifications									
6.	CT Number for Water	CT equipment or phantom manufacturers' specifications									
7.	Slice Thickness	CT equipment or phantom manufacturers' specifications									
8.	Field Uniformity	CT equipment or phantom manufacturers' specifications									
9.	Low Contrast Resolution	CT equipment or phantom manufacturers' specifications									
10.	High Contrast Resolution	CT equipment or phantom manufacturers' specifications									
11.	Noise	CT equipment or phantom manufacturers' specifications									
12.	Scan Protocol Review	Ensure that both the adult and pediatric scan protocols are separate and unique									
13.	Review of Facility and Technologist QC Tests	Review QC tests for proper procedure and corrective action									
14.	Physicist Report and Recommendations	Communicate results and recommendations to registrant									

Quality Assurance Program Review

Test frequency - Initially and annually thereafter

Standard - As required in N.J.A.C. 7:28-22.4(a)7

The Quality Assurance Program must be reviewed in its entirety to ensure that all information is current and accurate. The review must occur annually or after any equipment or personnel change. If personnel or operating procedures change frequently, reviews should be conducted more frequently to ensure that facility's Quality Assurance Program is maintained.

Physician should review the QA program when it is initially established, after each change in personnel, equipment or policy and annually. A good time for the review is right after the Medical Physicist performs the annual QC Survey. Any changes can be reviewed with the Medical Physicist.

Record on Form 2 Quality Control Log - Annual Tests (page 43).

NOTE: most of the following list is taken form the requirements in N.J.A.C. 7:28-22.4 and are contained in the facility's QA Program Manual. There are additional item listed that should be reviewed at least annually to ensure that the facility is in compliance with all applicable sections of N.J.A.C.7:28.

Quality Assurance Program Review Requirements

Review and update as necessary the following information:

- 1. List of clearly identified individuals and assigned responsibilities for maintaining the quality assurance program and for performing the quality control tests.
- 2. Quality Control (QC) measures
 - a. QC Tests to be performed and the frequency of each test
 - b. List of equipment to be tested
 - c. Acceptability limits for each test performed
 - d. Description of each QC test procedure
 - e. Sample forms for each QC test performed
 - f. Processor and solutions maintenance
 - g. Annual Medical Physicist's QC Survey
- 3. Policies and Procedures:
 - a. Policy for holding patients and for presence of individuals in room during radiation exposure
 - b. Policy for pregnant patients and employees
 - c. Policy for gonadal shielding
 - d. A description of the orientation program for operators of radiographic equipment including the duration and content of that program

- e. Procedures for proper use and maintenance of equipment
- f. Policies and employee responsibilities concerning personnel radiation monitoring
- g. Policy for releasing films
- h. Policy for labeling films (i.e., patient's statistics, facility information)
- i. A commitment to perform a Radiation Safety Survey of the Environs in accordance with N.J.A.C. 7:28-15.10 on newly installed x-ray equipment within 60 days of installation and an initial Medical Physicist's QC Survey as required by N.J.A.C. 7:28-22.8(a)
- j. Policy for using technique charts
- k. Policy and rules on Radiation Safety as required by N.J.A.C. 7:28-15.9(a) 8
- 4. Corrective actions
 - a. A plan for repairing or calibrating the x-ray equipment
 - b. A plan for repairing or servicing the processor
- 5. Records keeping:
 - a. Records for the most recent one year of the QC tests performed by the registrant
 - b. Records of the initial Medical Physicist's QC Survey plus the two most recent QC Surveys
 - c. Records of corrective actions for the most recent two years
 - d. Personnel monitoring records. Per New Jersey Administrative Code 7:28-8.1(f) records for each employee monitored must be maintained for the length of employment plus 10 years.
- 6. Reference manuals (if any) and their location.
- 7. A provision describing how the registrant and the qualified medical physicist will review the QA program annually.
- 8. Have you purchased new x-ray equipment either as a replacement or an additional unit? If so, did you:
 - a. Register it with the Bureau of Radiological Health within 30 days of installation? And
 - b. Have a qualified individual perform a Radiation Safety Survey of the Environs and submit a copy to the Bureau of Radiological Health within 60 days of installation?
 - c. Have an initial Medical Physicist QC Radiographic Survey performed within 30 days of installation?
- 9. Review of each **Registration of a Radiation Producing Machine** form to be sure the information is current. Questions to ask yourself:
 - a. Have you moved?
 - b. Are you the owner of record?
 - c. Has the facility contact person changed?
 - d. Is the x-ray machine on the Registration form the one you are currently using?
 - e. New Jersey Administrative Code 7:28-3 requires that the Bureau of Radiological Health be notified **in writing** within 30 days of a change of any of the information on the Registration form.
- 10. Review of the **Radiation Safety Survey of the Environs for each x-ray unit** to ensure it is current. Questions to ask yourself:
 - a. Has the location of the equipment been changed?
 - b. Has any change been made to the room in which the x-ray is located?
 - c. Has the number or type of x-rays taken increased significantly?
 - d. Has there been any change in what the rooms surrounding the x-ray room are used for?
 - e. Any such changes should be reviewed with your medical physicist to determine if a new

Radiation Safety Survey of the Environs needs to be performed. New Jersey Administrative Code 7:28 requires that a qualified individual perform a Radiation Safety Survey of the Environs and a copy submitted to the Bureau of Radiological Health within 60 days of any such change.

- 11. Are your registration fees paid for the current and previous year?
- 12. If any person other than a licensed practitioner takes x-rays, is each such person licensed as required by N.J.S.A. 26:2D-24 and N.J.A.C.7: 28-19? You may call 609-984-5890 to check the license status of any individual. Only a New Jersey licensed physician, podiatrist, or chiropractor, or a New Jersey licensed diagnostic radiologic technologist is permitted to operate any type of medical x-ray equipment and position patients for radiological procedures. "Operate" means the use or manipulation of x-ray equipment in any way that leads to or causes the emission of radiation or affects the amount or quality of radiation that is received by a patient. Examples of "operate" include, activating or terminating the x-ray exposure, setting or adjusting technical factors, setting the mode of imaging, setting the camera rate, and setting or adjusting the collimator. Tasks associated with turning on the x-ray equipment at the beginning of the day without a patient on the table, resetting the five minute timer, adjusting the imaging monitor, and post exposure data processing are not considered operating x-ray equipment. Please note: that the activation of the x-ray exposure for fluoroscopic procedures by a licensed diagnostic radiologic technologist is only permitted if a licensed physician is in the room and directing the fluoroscopic procedure. "Position patients" means the alignment of the x-ray tube, image receptor and the area of the patient intended for exposure to radiation.

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VENDORS LISTS

The following listing of vendors is supplied for informational purposes only. The State of New Jersey does not certify or license vendors. Inclusion in this list does not imply endorsement or recommendation by the New Jersey Department of Environmental Protection or any other state agency. A firm's name being absent from the list does not indicate that the Department has judged the firm unsuitable to provide services.

	Sensitometer and Densitometer Calibration Vendors											
Vendor Name and Phone No.	Recommended Frequency	Cost	Turnaround Time	Loaner Available								
Nuclear Associates 516-741-6360	annual	\$ 185	2 –3 weeks	Yes with a charge of \$ 82 for each 30 days for either a sensitometer or a densitometer								
Innovision 800-850-4606	annual	\$ 135	1 –2 weeks	Limited number of loaners available. First come - first served								
X Rite 616-534-7663	annual	\$ 120 and up depending on model	1 week	Limited number of loaners available. First come - first served								
JRT 610-327-9610	annual	\$ 150 and up depending on model	2 - 3 weeks	No								

VENDOR LIST for QUALITY ASSURANCE SUPPLIES												
Company	Address	City	St	Zip Code	Phone	Fax						
American Imaging Systems, Inc.	3001 Hadley Rd Suite 5A	South Plainfield	NJ	07080	800-762-2901							
Andrews & Walsh X-ray Inc.	55 Cannonball Rd	Pompton Lakes	NJ	07442	973-616-7100							
Cares Medical, Inc.	75 Manchester Ave	Key Port	NJ	07735	732-739-8900	732-739-0316						
Diagnostic Imaging, Inc.	8015 Rt. 130 S.	Delran	NJ	08075	856-461-4261							
Elscint, Incorporated	86 Orchard Ave	Hackensack	NJ	07601	201-750-3240							
GE Medical Systems, Inc	PO Box 414, SM 471	Milwaukee	WI	53225	800-558-5102							
GE Medical Systems, Inc	PO Box 1561	King of Prussia	PA	19406	610-992-6400							
Hi-Tech X-ray Inc.	2 Oak St	New Brunswick	NJ	08901	732-448-9729	732-448-9733						
Marconi Medical Systems	4 Esterbrook Lane	Cherry Hill	NJ	08003	856-424-3620							
Marconi Medical Systems (Picker Int)	595 Miner Rd	Highland Heights	ОН	44143	800-635-9729							
Marconi Medical Systems (Picker Int)	2520 Metropolitan Dr.	Trevose	PA	19053	215-322-9300							
Med-X Imaging, Inc	1102 Industrial Parkway	Brick	NJ	08724	732-458-4144	732-458-4334						
Metropolitan X-ray Supply	28 Eaton Rd	Eatontown	NJ	07724	732-544-9272	732-544-1845						
New Jersey X-ray Corporation	40 Schuyler Ave.	Kearny	NJ	07032	201-998-0900	201-998-3903						
Nuclear Associates	lear Associates 100 Voice Rd PO Box 349		NY	11514	888-466-8257							
Phillips Medical Systems	150 Clearbrook Rd	Elmsford	NY	10523	800-833-3316							
Smith-Chapman Inc.	PO Box 378	Kearny	NJ	07032	201-998-8877	201-998-0988						
Standard X-ray Sales Co.	60 Coit St.	Irvington	NJ	07111	973-374-2400	973-374-8435						
United X-ray Inc.	1 Todd Circle	No Brunswick	NJ	08902	732-381-0407							
X-Rite, Incorporated	3100 44th Street, SW	Grandville	MI	49418	616-534-7663	616-534-8960						

Options For When The Facility's Densitometer Is Unavailable

The NJ regulation specifies that laser printer QC MUST be performed weekly.

The facility must ensure that if the densitometer is broken, out for calibration, or otherwise unavailable that a substitute instrument is available or another procedure is in place to ensure that the laser film printer is operating within control limits.

The options given below are a TEMPORARY solution for times when the densitometer is unavailable. They are not to be used for longer than three weeks.

A facility should consult with their medical physicist or image consultant to determine which of the listed options is best for their facility. It is also possible for the medical physicist or image consultant to design another option for the facility to use while its densitometer is unavailable. Any such option must ensure that the laser film printer is operating within control limits.

NOTE: It may be necessary to perform Procedure 3A (Establishment of Laser Printer Quality Control Operating Levels) after the densitometer is calibrated or repaired if the density of the patches have changed significantly.

Below is a list of options the facility may consider for meeting this requirement.

- 1. Obtain a loaner densitometer from a processor service company, the calibration company or arrange to use a colleague's. The facility must perform the following procedure to ensure that the Laser Printer Control Chart does not indicate an out of control laser film printer due to the use of a different densitometer.
 - a. Dr. A has to return his densitometer for service. Dr. A asks Dr. B (whose office is in the building next door) if he can use Dr. B's densitometer. Dr. B agrees.
 - b. Dr. A prints and processes a SMPTE test pattern film as usual and takes it to Dr. B's office BEFORE performing any patient x-rays.
 - c. Dr. A reads the 0%, 10%, 40% and 90% patches using Dr. B's densitometer.
 - d. Dr. A compares the readings obtained in (c) to the readings he got previously with his own densitometer.
 - e. If the previous reading for the 10% patch was 0.53 and the 40% patch read with Dr. B's densitometer is 0.5, Dr. A will have to add 0.03 to all readings from Dr. B's densitometer in order to have comparable readings for his Laser Printer QC chart. If the readings indicate that Dr. A's processor is out of control, Dr. A must correct the problem and perform steps (a) through (e) again to ensure his processor is operating within limits.
- 2. Purchase two densitometers.
- 3. Send patients to another facility to have their x-rays.
- 4. Take no patient x-rays when facility has no operable/in calibration densitometer.

Form 1 Laser Film Printer Control Chart

Year:		Laser	Film Pr	inter: _					Fi	lm: _						_	
Month																	
Day																	
Initials																	
0%	2.6																
	2.45																
	2.3																
100/	2.25	 				I					l			l			
10%	2.25																
		+ +															
	2.10																
	2.10																
	1.95																
			'I	ı		1					ı			ı			
40%	1.30																
	1.15																
	1.00																
	0.20 ::::					.1											
90%	0.38																
	0.3																
	0.22																
	<u>.</u>	1 1		1	1	1	1	1	1	1	1	1	1	1	1	1	
5% visible in 0	%																
95% visible in																	
				•	•	•	•	•	•	•	•	•	•	•	•	•	
Date						Re	marks	s/Acti	on Ta	ken							

Date	Remarks/Action Taken

Form 2	Quality	Control 3	Log -	Annual	Tests
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Each time a listed procedure is completed, person performing it must fill in date, their initials and note if equipment passed or failed. If equipment failed, the appropriate person(s) must be notified and corrective action taken. Procedure should be repeated after correction to ensure that equipment now passes. Performance and results of repeat tests should be listed on chart.

P = PASS	F = FAILED	Y = YES	 N = 1	OV					
Lead aprons,	Date								
gloves, gonadal	Preformed by								
and thyroid shielding integrity check	If equipment failed, appropriate person(s) notified								
Medical Physicist's	Date								
QC Survey	Preformed by								
Procedure Page 30	If problems found, appropriate person(s) notified								
Quality Assurance Program Review Procedure Page 32	Date								
	Preformed by								
	If problems found, appropriate person(s) notified								

Comments can be recorded on reverse of form.